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PC10240A/EDJ

MAY 07 2001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TECH CENTER 1600/2900

IN RE APPLICATION OF: :
MCCLURE ET AL. : Examiner: Weber, J.
SERIAL NO.: 09/373,182 : Art Unit: 1651
FILED: AUGUST 12, 1999 :
FOR: TACE INHIBITORS

7/a
H. J.
5/9/01

Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

RESPONSE TO RESTRICTION REQUIREMENT UNDER 37 CFR § 1.143

This document responds to an Office Action mailed December 1, 2000, requiring a response by January 1, 2001. A Petition for a four-month extension of time accompanies this document. If such Petition is granted the period in which to respond will expire on May 1, 2001.

Claims 1-79 are pending in the application. Claims 1-79 are subject to restriction and election requirements. Reconsideration of the restriction requirement is respectfully requested. Additionally, in response to a request by the Examiner, Applicants attach hereto a diskette containing sequence listing. ✓

The Examiner has imposed a thirteen way restriction in the present application (Groups I-XIII), and additionally, requires Applicants to elect a single species to begin prosecution. The Groups I-XIII required by the Examiner, along with the required fields of search, are tabulated below:



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Group I	Claims 1-54	Hydroxamate compounds and compositions	-----	Class subclasses 8, 59, 106
Group II	Claim 55	A method of inhibiting TNF productions	with the compounds of claim 1	Class 514, subclasses 227.5, 231.2, 255
Group III	Claims 56, 59	A method of treating diseases	with the compounds of claim 1	Class 514, subclasses 227.5, 231.2, 255
Group IV	Claims 57-58	A method of inhibiting TNF cleavage	with the compounds of claim 1	Class 435, subclass 212
Group V	Claims 60-61	A method of inhibiting TNF cleavage	with compounds that inhibit TACE > MMP-1	Class 435, subclass 183+
Group VI	Claims 62, 66-67	A method of treating diseases	with compounds that inhibit TACE > MMP-1	Class 514, subclass ?
Group VII	Claims 63-64	A method of inhibiting TNF cleavage	with compounds that inhibit TACE > MMP-13	Class 514, subclass ?
Group VIII	Claim 65	A method of inhibiting TNF cleavage	with compounds that inhibit TACE and aggrecanase > MMP-1	Class 514, subclass ?
Group IX	Claims 68-69	A method of treating arthritis	with compounds that inhibit TACE and MMP-13 > MMP-1	Class 514, subclass ?
Group X	Claims 70-71	A method of treating arthritis	with compounds that inhibit aggrecanase > MMP-1	Class 514, subclass ?
Group XI	Claims 72-75	A method of treating arthritis	with compounds that inhibit aggrecanase and MMP-13 > MMP-1	Class 514, subclass ?
Group XII	Claims 76-77	A method of treating arthritis	with compounds that inhibit aggrecanase and TACE > MMP-1	Class 514, subclass ?
Group XIII	Claims 78-79	A method of treating arthritis	with compounds that inhibit aggrecanase, TACE and MMP-13 > MMP-1	Class 514, subclass ?

Applicants provisionally elect with traverse Group (claims 60-61). Applicants also elect the species 4-acetyl-3-methyl-1-[4-(2-methyl-benzyloxy)-benzenesulfonyl]-piperazine-2-carboxylic acid hydroxyamide for initial examination.

Applicants respectfully traverse the Examiner's restriction on the grounds that such restriction is improper and an abuse of discretion because prosecution of the restricted subject matter in one application would not place a serious burden on the Examiner. According to M.P.E.P. § 803 the Examiner can only restrict patentably distinct inventions when (1) The inventions are independent or distinct as claimed and (2) Where there is a serious burden on the Examiner if restriction is not required.

Applicants respectfully submit that the Examiner has made no showing that prosecuting all present claims in one application would be seriously burdensome. Applicants therefore submit that the Examiner's requirement of restriction into thirteen groups (i.e Groups I-XIII) based only upon his alleged showing that the inventions as claimed are independent and distinct is erroneous.

1. Reconstitution of Claims

Even though Applicants maintain that they are entitled to prosecution of all claims in one application, in the interest of expediting prosecution, Applicants herein propose a revised restriction that they could accept. Specifically, Applicants propose that the claims be restricted into the following three, rather than thirteen, groups:

Proposed Group I	Claims 1-59	Hydroxamate compounds claim, composition claims, and method of use claims, wherein claims 2-59 are dependent from claim 1	Classes 544, 514, and 435
Proposed Group II	Claims 60-69	Field of use claims utilizing small molecules, a hydroxamic acid compound, or an agent that inhibit the proteolytic activity of TACE selectively over MMP-1	Classes 435 and 514
Proposed Group III	Claims 70-79	Field of use claims utilizing aggrecanase inhibitors, a hydroxamic acid compound, or an agent that inhibit the activity of aggrecanase selectively over MMP-1	Class 514

In the event that the Examiner maintains the restriction requirement, thereby refusing the proposed reconstitution, Applicants respectfully submit that they will be forced to petition the Commissioner to consider the thirteen-way restriction. In anticipation of such an unfortunate outcome, Applicants herein submit that the above proposed reconstitution of the restriction requirement is not an admission that there is any burden imposed by prosecuting all the pending claims as originally filed. Applicants have merely made a proposal in order to expedite prosecution so that they may secure their valuable patent right at as early a date as practicable.

If the Examiner accepts the proposed reconstitution, Applicants would elect the proposed Group II (i.e. claims 60-69), which is consistent with the election made above (i.e. claims 60 and 61 of Group V) additionally reasonably including claims 62-69.

2. Burden

Applicants respectfully submit that the proposal of reconstitution is not an admission that there is a serious burden with prosecuting all claims in one application. In contrast, Applicants submit that searches for any of the Examiner's Groups I-XIII or Applicants' proposed Groups I-III would require a search of the same classes and subclasses and thus cannot support an allegation of burden. The Examiner's suggestion that the Examiner's Groups I-XIII require different fields of search is only applicable to his allegation of "independent and distinct" invention. It is not applicable to "burden".

In discharging his obligation to conduct a diligent search, the Examiner must search all classes and subclasses that may have material pertinent to the subject matter as claimed. M.P.E.P. 904.02(a) states that:

"In outlining a field of search, the Examiner should note every class and subclass under the U.S. Patent Classification System and other organized systems of literature that may have material pertinent to the subject matter as claimed. Every subclass, digest, and cross reference art collection pertinent to each type of invention claimed should be included, from the largest combination through the various sub-combinations to the most elementary part. The fields of search should extend to all probable areas relevant to the claimed subject matter and should cover the disclosed features which might reasonably be expected to be claimed..." (emphasis added)

Applicants have disclosed in the specification that the compounds of the invention possess the claimed features (i.e., compositions and methods of use). It might therefore be reasonable to expect that each of the classes and subclasses identified in each group of the Examiner's Groups I-XIII extend to areas relevant to the claimed subject matter of any other groups. To support their arguments that all the required classes and subclasses are pertinent for any of the Examiner's

Groups I-XIII, Applicants respectfully submit the following analysis.

First, according to the above cited M.P.E.P. 904.02(b), the Examiner is required to search all pertinent classes and sub-classes to determine the patentability of any of Groups I to IV (Claims 1-59) because the claims of Groups II-IV (Claims 55-59) are dependent from claim 1. The Examiner reported that the required field of search for Groups I-IV is class 544 (directed to organic compounds), class 514 (directed to drug, body affecting, and body treating compositions), and class 435 (directed to chemistry: molecular biology and microbiology). M.P.E.P. 904.02(b) suggests that the field of search may be of multiple classes and therefore the three relevant classes alone do not per se prove that the search is seriously burdensome. In fact, as written in the Office Action, Groups II and III require the same exact field of search (i.e., class 514, subclasses 227.5, 231.2 and 255). The methods of use claims of Groups II-IV call for the compounds of the formula I (i.e. the compounds of claim 1) which are prepared by the methods of Schemes 1-4 of the specification. Therefore, all references relevant to compounds of claim 1 uncovered in the Group I search would also be the appropriate references in the Group II-IV searches.

Second, Applicants further submit that the search of the classes and subclasses of the Examiner's Groups V is pertinent to the search of Groups I-IV. The claims of Group V are drawn to a method of inhibiting TNF cleavage, which as reported by the Examiner, requires a search of class 435, subclass 183+ (directed to enzyme (e.g., ligases (6.), etc.), proenzyme; compositions thereof; process for preparing, activating, inhibiting, separating, or purifying enzymes). Applicants respectfully submit that class 435, subclass 212 (directed to enzyme (e.g., ligases (6.), etc.), proenzyme; compositions thereof; process for preparing, activating, inhibiting,

separating, or purifying enzymes acting on peptide bond (e.g., thromboplastin, leucine amino-peptidase, etc., (3.4))), was a required field of search for the claims of the Examiner's Group IV. As the Examiner can see, subclass 212 is actually a narrower sub-class of sub-class 183. Thus searching for both subclasses 212 and 183 in each of the Examiner's Groups I-V is required and cannot be seriously burdensome.

Third, Applicants further submit that the search of the claims of the Examiner's Groups VI-XIII are relevant to the search of Groups II and III. The claims of groups VI-XIII constitute field of use claims drawn to either methods of inhibiting cleavage of TNF or methods of inhibiting diseases, such as arthritis, classified in class 514 (directed to organic compounds). Applicants respectfully submit that since class 514 was a required field of search for the Examiner's Groups II and III, the Examiner would have all the necessary references to prosecute claims of Groups VI-XIII in front of him.

In conclusion, Applicants respectfully submit that all Claims 1-79 require relevant classes and subclasses in their field of search and the Examiner has not met his burden to show that the search for all Claims 1-79 would be seriously burdensome.

3. Administrative Burden

Applicants further traverse the restriction of claims among the Examiner's Groups I-XIII on the grounds that such a rejection would lead to an increase in the administrative burden on the Patent Office. Such increase in the administrative burden is contrary to the directive of the Commissioner to expedite the prosecution of applications and remove the backlog of applications in the patent office.

In compliance with the Commissioner's goals, in the present situation, the entire application should be prosecuted as a whole and allowed within a reasonable time. The

Examiner's restrictions of claims among Groups I-XIII would potentially have the effect that Applicants would be denied claims because they would not issue until the end of patent terms.

Applicants further submit that prosecution of three applications as the Applicants have proposed above would already be administratively burdensome. However, prosecuting thirteen applications as the Examiner proposed would be an abuse of the Patent Office Resources.

4. Conclusions

For the above reasons, withdrawal of the restriction requirement with respect to Groups I-XIII is requested, and, if that restriction is maintained, reconstitution of the restriction requirement to Groups I-III, is requested.

Date: May 1 '01

Respectfully submitted,



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Organisms: Artificial Sequence

Sequence 1

Mca-Pro-Leu-Gly-Leu-Dpa-Ala-Arg-NH₂

Sequence 2

Dnp-Pro-Cha-Gly-Cys(Me)-His-Ala-Lys(NMA)-NH₂

Sequence 3

Ac-Pro-Leu-Gly-SCH[CH₂CH(CH₃)₂]CO-Leu-Gly-OC₂H₅

Sequence 4

LY-Leu-Ala-Gln-Ala-Val-Arg-Ser-Ser-Lys(CMTR)-Arg
(LY=Lucifer Yellow; CMTR= 5-carboxytetramethyl Rhodamine))